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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,720	01/15/2004	Harm M. Deckers	9369-289	3856

1059 7590 11/14/2007

BERESKIN AND PARR
40 KING STREET WEST
BOX 401
TORONTO, ON M5H 3Y2
CANADA

EXAMINER	
HORNING, MICHELLE S	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
11/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/757,720	DECKERS ET AL.	
	Examiner	Art Unit	
	Michelle Horning	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 January 2004 and 10 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

\This office action is responsive to communication filed 1/10/2005. The status of the claims is as follows: claims 1-7 are under current examination.

Specification

The disclosure is objected to because of the following informalities: the continuing data in both the specification and the Application Data Sheet is outdated.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "plant cell" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Parmenter et al (1995). The limitations of the rejected claims above are as follows:

1. A method for preparing an immunogenic formulation comprising oil bodies and an antigen, said method comprising:

(a) producing an antigen in a cell;

(b) associating said antigen with oil bodies through an oil body targeting protein capable of associating with said antigen and said oil bodies;

(c) obtaining the oil bodies associated with the antigen;

(d) washing the oil bodies to obtain washed oil body preparation comprising the antigen; and (e) formulating the washed oil bodies associated with the antigen into an immunogenic formulation.

2. A method according to claim 1 wherein said oil body targeting protein is an oil body protein.

3. A method according to claim 1 wherein said oil body protein is an oleosin.

4. A method for preparing an immunogenic formulation according to claim 1 wherein the antigen is produced in a cell and associated with oil bodies through an oil body targeting protein capable of associating with said antigen and said oil bodies, according to a method comprising: (a) introducing into a cell a chimeric nucleic acid sequence comprising: (1) a first nucleic acid sequence capable of regulating transcription in said cell operatively linked to; (2) a second nucleic acid sequence encoding a recombinant fusion polypeptide comprising (i) a first nucleic acid sequence

encoding a sufficient portion of an oil body protein to provide targeting to an oil body linked in reading frame to (ii) a second nucleic acid sequence encoding an antigen operatively linked to; (3) a third nucleic acid sequence capable of terminating transcription in said cell; and (b) growing said cell under conditions to permit expression of said antigen in a progeny cell comprising oil bodies.

5. A method according to claim 4 wherein said oil body protein is an oleosin.

6. A method according to claim 4 wherein said chimeric nucleic acid sequence is introduced into a plant cell.

Parmenter et al disclose the production of hirudin in plant seeds using oleosin partitioning (see title and whole document). Oleosin was used as a 'carrier' for the production of hirudin protein (see abstract). Hirudin is produced in the salivary glands of a leech and is a potent and specific thrombin inhibitor. Further, this protein is being studied for its use as a blood anticoagulant (see second column, page 1168). Figure 1B reveals the linear DNA construct for the oleosin-hirudin fusion protein. More specifically, the "oleosin-hirudin fusion gene is under the control of an *Arabidopsis* oleosin promoter (838 bp), and is terminated by a 267 bp nopaline synthase transcriptional terminator (NOS)" (see figure legend, page 1169). This reference demonstrates "the efficacy of using oleosin gene fusions for the production of high-value recombinant proteins in plants". Also disclosed is that the corresponding fusion proteins was detected in dry seeds and was localized primarily to the oil body phase of centrifuges seed proteins (see Discussion); thus, hirudin is associated to the oil bodies.

Of note, the instant specification defines the term "washing the oil bodies" as any process that removes cellular contaminants or undesirable properties and such methods may include separation methods such as centrifugation (paragraph 55). This limitation is met by this prior art reference which specifically teaches centrifugation techniques to remove insoluble fractions (see *Isolation and extraction of seed proteins*, page 1170). Lastly, this prior art reference concludes with the following recitation: "In conclusion, we have described a system for the general production and recovery of recombinant peptides synthesized as fusions to seed oil body proteins. The fidelity of this system has been demonstrated with the production of a functional pharmaceutical protein, hirudin. The system is flexible with respect to the different types of proteins it can accommodate and enables rapid and simple purification of the recombinant product. Furthermore, low cost of seed production and compatibility with existing agricultural processing procedures make it an attractive alternative to conventional bacterial and yeast fermentation systems" (see page 1178).

Also noted is that the instant specification defines an antigen as "any molecule to which one wishes to elicit an immune response" (see paragraph 160). Further, paragraph 129 provides the following teaching: "The scope of the invention is not limited by the type of antigen used or the means by which the antigen is produced. Antigens may consist of peptides, proteins, carbohydrate or synthetically produced chemicals. The antigen may be similar or identical to the natural molecule against which an immune response is desired or may simply resemble the natural molecule sufficiently to be able to induce a response against the natural molecule. Due to the wide range of

possibilities for production and use of antigens it is impossible to provide a comprehensive list of potential antigens that could be included in immunizations with oil bodies and thus only examples that may be reflective of the type of antigens that could be considered are provided." Thus, an antigen can be anything. All of the limitations have been met by the prior art.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5948682 (cited, hereinafter as "Moloney"). The limitations of the rejected claims above are as follows:

1. A method for preparing an immunogenic formulation comprising oil bodies and an antigen, said method comprising:

(a) producing an antigen in a cell;

(b) associating said antigen with oil bodies through an oil body targeting protein capable of associating with said antigen and said oil bodies;

(c) obtaining the oil bodies associated with the antigen;

(d) washing the oil bodies to obtain washed oil body preparation comprising the antigen; and (e) formulating the washed oil bodies associated with the antigen into an immunogenic formulation.

2. A method according to claim 1 wherein said oil body targeting protein is an oil body protein.

3. A method according to claim 1 wherein said oil body protein is an oleosin.

4. A method for preparing an immunogenic formulation according to claim 1 wherein the antigen is produced in a cell and associated with oil bodies through an oil body targeting

protein capable of associating with said antigen and said oil bodies, according to a method comprising: (a) introducing into a cell a chimeric nucleic acid sequence comprising: (1) a first nucleic acid sequence capable of regulating transcription in said cell operatively linked to; (2) a second nucleic acid sequence encoding a recombinant fusion polypeptide comprising (i) a first nucleic acid sequence encoding a sufficient portion of an oil body protein to provide targeting to an oil body linked in reading frame to (ii) a second nucleic acid sequence encoding an antigen operatively linked to; (3) a third nucleic acid sequence capable of terminating transcription in said cell; and (b) growing said cell under conditions to permit expression of said antigen in a progeny cell comprising oil bodies.

5. A method according to claim 4 wherein said oil body protein is an oleosin.

6. A method according to claim 4 wherein said chimeric nucleic acid sequence is introduced into a plant cell.

7. A method according to claim 1 wherein said plant cell is a safflower cell.

Moloney discloses a method in preparing heterologous proteins on oil bodies (see title and abstract). More specifically, the method includes producing polypeptides fused to oil body proteins, like oleosins, (see columns 30-37, Examples 7-14) in various plant species, including safflower (see column 38, Example 16). The following recitation with respect to the chimera DNA sequence is made : "The present invention also provides a chimeric DNA sequence encoding a fusion polypeptide, capable of being expressed in association with an oil body of a host cell comprising: 1) a first DNA sequence

capable of regulating the transcription in said host cell of 2) a second DNA sequence, wherein said second sequence encodes a fusion polypeptide and comprises (i) a DNA sequence encoding a sufficient portion of an oil body protein gene to provide targeting of the fusion polypeptide to a lipid phase linked in reading frame to (ii) a DNA sequence encoding a heterologous polypeptide; and 3) a third DNA sequence encoding a termination region functional in the host cell." Regarding heterologous proteins, Moloney makes the following recitation in column 18, paragraph 4: "Of particular interest are those proteins or peptides that may have a therapeutic or diagnostic value. These proteins include antigens, such as viral coat proteins or microbial cell wall or toxin proteins or various other antigenic peptides, peptides of direct therapeutic value such as interleukin-1-.beta., the anticoagulant hirudin, blood clotting factors and bactericidal peptides, antibodies, specifically a single-chain antibody comprising a translational fusion of the VH or VL chains of an immunoglobulin. Human growth hormone may also be produced. The invention is not limited by the source or the use of the heterologous polypeptide."

As noted above, the instant specification defines the term "washing the oil bodies" as any process that removes cellular contaminants or undesirable properties and such methods may include separation methods such as centrifugation (paragraph

55). This prior art reference provides methods for the separation of heterologous proteins from host cell components by partitioning of the oil body fraction (see column 7, paragraph 3). Thus, all of the limitations of the claims have been met.

Conclusions

NO claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michelle Horning
Patent Examiner.

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600